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Docket No.: 1110-0339PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Toshihiko KAKIUCHI

Application No.: 10/561,274

Confirmation No.:

Filed: December 19, 2005

Art Unit: N/A

For: COMPOSITION FOR PREVENTING AND  
TREATING VARICOSE VEINS OF LOWER  
EXTREMITIES

Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on December 19, 2005, attached hereto is an English translation of the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any


Application No.: 10/561,274

Docket No.: 1110-0339PUS1

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: June 8, 2006

Respectfully submitted,

By  #42874  
Gerald M. Murphy, Jr.  
Registration No.: 28,977  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Attachment(s) PCT/IB/338,PCT/IB/373,PCT/ISA/237

## PATENT COOPERATION TREATY

PCT/JP2004/008944

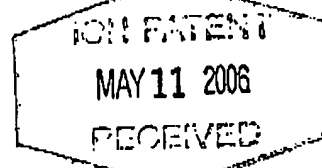
From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

WATANABE, Mochitoshi  
Hayakawa-tonakai Bldg. 3F, 12-5, Iwamoto-cho 2-chome,  
Chiyoda-ku, Tokyo  
1010032  
JAPON



Date of mailing (day/month/year) 04 May 2006 (04.05.2006)	
Applicant's or agent's file reference W-3585PCT	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/008944	International filing date (day/month/year) 18 June 2004 (18.06.2004)
Applicant MOCHIDA PHARMACEUTICAL CO., LTD. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No. +41 22 740 14 35	Facsimile No. +41 22 338 90 90

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference W-3585PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/008944	International filing date (day/month/year) 18 June 2004 (18.06.2004)	Priority date (day/month/year) 20 June 2003 (20.06.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant MOCHIDA PHARMACEUTICAL CO., LTD.			

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 6 sheets, including this cover sheet.  
  
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
- This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Date of issuance of this report 24 April 2006 (24.04.2006)
	Authorized officer  Yoshiko Kuwahara  Telephone No. +41 22 338 90 90

## PATENT COOPERATION TREATY

TRANSLATION

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

W-3585PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/008944

International filing date (day/month/year)

18.06.2004

Priority date (day/month/year)

20.06.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

MOCHIDA PHARMACEUTICAL CO., LTD.

## 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b(a)(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

## 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/008944

Box No. I	Basis of this opinion
1.	<p>With regard to the language, this opinion has been established on the basis of the International application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).</p>
2.	<p>With regard to any nucleotide and/or amino acid sequence disclosed in the International application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> in written format</p> <p><input type="checkbox"/> in computer readable form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed.</p> <p><input type="checkbox"/> filed together with the international application in computer readable form.</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.</p>
3.	<p><input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p>
4.	<p>Additional comments:</p>

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/008944

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 6

because:

☒ the said international application, or the said claims Nos. 6  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 6 pertains to methods for treatment of the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 6

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		International application No. PCT/JP2004/008944																								
<b>Box No. V</b>	<b>Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</b>																									
<p><b>1. Statement</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;">Novelty (N)</td> <td style="width: 40%;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Claims</td> <td style="border-bottom: 1px solid black; width: 50%;"></td> <td style="width: 40%; text-align: right;">YES</td> </tr> <tr> <td>Claims</td> <td style="border-bottom: 1px solid black;">1-5</td> <td style="text-align: right;">NO</td> </tr> </table> </td> </tr> <tr> <td style="vertical-align: top;">Inventive step (IS)</td> <td> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Claims</td> <td style="border-bottom: 1px solid black; width: 50%;"></td> <td style="width: 40%; text-align: right;">YES</td> </tr> <tr> <td>Claims</td> <td style="border-bottom: 1px solid black;">1-5</td> <td style="text-align: right;">NO</td> </tr> </table> </td> </tr> <tr> <td style="vertical-align: top;">Industrial applicability (IA)</td> <td> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Claims</td> <td style="border-bottom: 1px solid black; width: 50%;"></td> <td style="width: 40%; text-align: right;">YES</td> </tr> <tr> <td>Claims</td> <td style="border-bottom: 1px solid black;">1-5</td> <td style="text-align: right;">NO</td> </tr> </table> </td> </tr> </table>			Novelty (N)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Claims</td> <td style="border-bottom: 1px solid black; width: 50%;"></td> <td style="width: 40%; text-align: right;">YES</td> </tr> <tr> <td>Claims</td> <td style="border-bottom: 1px solid black;">1-5</td> <td style="text-align: right;">NO</td> </tr> </table>	Claims		YES	Claims	1-5	NO	Inventive step (IS)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Claims</td> <td style="border-bottom: 1px solid black; width: 50%;"></td> <td style="width: 40%; text-align: right;">YES</td> </tr> <tr> <td>Claims</td> <td style="border-bottom: 1px solid black;">1-5</td> <td style="text-align: right;">NO</td> </tr> </table>	Claims		YES	Claims	1-5	NO	Industrial applicability (IA)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Claims</td> <td style="border-bottom: 1px solid black; width: 50%;"></td> <td style="width: 40%; text-align: right;">YES</td> </tr> <tr> <td>Claims</td> <td style="border-bottom: 1px solid black;">1-5</td> <td style="text-align: right;">NO</td> </tr> </table>	Claims		YES	Claims	1-5	NO
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Claims	1-5	NO																								
<p><b>2. Citations and explanations:</b></p> <p>The following documents appear in the ISR.</p> <p>Document 1/JP 2002-539138 A  Document 2/JP 6-298642 A  Document 3/JP 7-25816 A  Document 4/WO 2001/84961 A2  Document 5/Nanzando, Igaku Daijien, (Gokaban) Dai 18 Han, Nanzanko, 1998, p. 981  Document 6/JP 2000-502081 A  Document 7/JP 4-226915 A  Document 8/JP 2000-510006 A</p> <p>(1) Novelty/Inventive Step of Claims 1 and 2/Documents 1-3  Documents 1-3 describe food products and cosmetics containing icosapentate and derivatives thereof.</p> <p>(2) Novelty/Inventive Step of Claims 3-5/Documents 4-6  Document 4 describes a therapeutic agent for varicose veins containing icosapentate and derivatives thereof such as (tri) glyceride, and varicose veins in the legs are the predominant type of varicose veins as described in documents 5 and 6.  Consequently, the invention of the present application is identical to that described in document 4.</p> <p>(3) Inventive Step of Claims 3-5/Documents 2-4 and 6-8  Documents 4 and 7 describe inhibition of (vascular epithelial) inflammation by icosapentate, and documents 6 and 8 describe inflammation as a causal factor of varicose veins and valve incompetence.  Further, from documents 2-4, icosapentate and derivatives thereof such as the ethyl ester thereof are acknowledged to possess the same pharmacological activity.</p> <p style="text-align: right;">(Continued)</p>																										



WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/008944

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Consequently, based on the descriptions of documents 2-4 and 6-8, use of a compound that inhibits inflammation with icosapentate or the ethyl ester thereof for the prevention/treatment of varicose veins in the legs would be obvious to a person skilled in the art.